

REMARKS

Claims 1-39 are pending in this application upon entry of this amendment. Claims 9-38 have been withdrawn. Claims 1-9 and 38 are currently under examination on the merits. No new matter has been added.

I. Election/Restriction

Applicants would like to thank the Examiner for extending the scope of the examination to include compounds of Formula I wherein Y and/or X are C₁-C₂₂ alkyl, C₂-C₂₂ alkenyl, and C₂-C₂₂ alkynyl.

II. Information Disclosure Statement

The Office Action stated that references C10, C40 and C99 of the PTO Form 1449 were not considered because they failed to provide a date of publication. Applicants submit concurrently herewith another PTO Form 1449 that provides these three references with their corresponding dates of publication. Applicant requests that the Examiner consider the references and mark and return the form.

III. The Rejections Under 35 U.S.C. § 112, First Paragraph, Should be Withdrawn

Claims 1-8 and 39 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Office Action alleges the claims contain subject matter, which was not described in the specification in such a way as to convey that the inventor had possession of the claimed invention at the time the application was filed.

Specifically, the Office Action alleges that the specification provides no direction or guidance as to what constitutes a “prodrug.” Without acquiescing to the merits of the rejection, Applicants have amended the claims to remove recitation of the phrase “prodrug.” Accordingly, Applicants respectfully request that this rejection be withdrawn.

IV. The Rejection under 35 U.S.C. § 103(a) Should be Withdrawn

Claims 1-8 and 39 are rejected under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent No. 5,962,437 to Kucera *et al.* (“Kucera”).

The Federal Circuit has set forth three basic criteria that must be met to establish a case of *prima facie* obviousness. First, there must have been at the time of the invention a motivation to combine or modify the teachings of the references cited. *Ecolochem, Inc. v. Southern California Edison Company*, 227 F.3d 1361, 1372 (Fed. Cir. 2000) (holding obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination); *see also In re Jones*, 958 F.2d 347 (Fed. Cir. 1992); *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988) (holding that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art). Second, the alleged prior art must teach or suggest all of the limitations of the claims alleged to be obvious. *In re Royka*, 490 F.2d 488 (CCPA 1974) (holding that to establish *prima facie* obviousness of a claimed invention, all of the claim limitations must be taught or suggested by the prior art); *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991) (holding that the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in the applicant’s disclosure). Third, there must have been at the time of the invention a reasonable expectation of success. *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1207-1208 (Fed. Cir. 1991), *cert. denied* 502 U.S. 856 (1991) (holding that obviousness requires references to show that there was, at the time of the invention, a reasonable expectation of success).

The U.S. Supreme Court has ruled in a unanimous opinion that a “narrow” and “rigid” TSM [teaching, suggestion, motivation] test is not the proper application of the non-obviousness doctrine of Section 103(a) of the Patent Act. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007). According to the Supreme Court, “[t]o facilitate review, [the obviousness] analysis should be made explicit. But it need not seek out precise teachings directed to the challenged claim’s specific subject matter, for a court can consider the inferences and creative steps a person

of ordinary skill in the art would employ.” The Court further elucidated, “[a] patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art.” “There is no necessary inconsistency between the [teaching, suggestion, motivation] test and the Graham analysis. But a court errs where it transforms general principle into a rigid rule limiting the obviousness inquiry.” The Federal Circuit stated that the test for *prima facie* obviousness in an invention concerning chemical compounds “is consistent with the legal principles enunciated in *KSR*,” and thus, “in cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish a *prima facie* obviousness of a new claimed compound.” *Takeda Chemical Industries, LTD et al. v. Alphapharm PTY., Ltd.*, 492 F.3d 1350 (Fed. Cir. 2007).

The Office Action alleges that Kucera discloses treating viral infections by administering a phospholipid or phospholipid derivative. More particularly, the Office Action alleges that Kucera anticipates the claimed compounds of Formula I, and further that Kucera motivates those skilled in the art to use the compounds of Formula I to treat viral infections.

The formula disclosed by Kucera requires a NHCO , CH_3NCO , CONH , CONCH_3 , S , SO , SO_2 , O , NH or NCH_3 covalently bonded to a $\text{C}_6\text{-C}_{14}$ alkyl group that is optionally substituted at a position comparable to R_2 of Formula I of the claimed invention. The claims, as amended, provide that R_2 is an O covalently bonded to a $\text{C}_1\text{-C}_5$ alkyl, $\text{C}_2\text{-C}_5$ alkenyl, or $\text{C}_2\text{-C}_5$ alkynyl.

The Office Action alleges that Kucera discloses treating RSV with the compounds of the invention and further that Kucera motivates those skilled in the art to use the compounds disclosed by Kucera to treat various types of virus. However, Kucera does not disclose or suggest the compounds of the claimed invention, as amended, nor provide suggestion or motivation to utilize shorter branched alkyl, alkenyl or alkynyl groups. Indeed, Kucera is silent with regard to compounds where R_2 is an O coupled to a $\text{C}_1\text{-C}_5$ alkyl, $\text{C}_2\text{-C}_5$ alkenyl, or $\text{C}_2\text{-C}_5$ alkynyl. Moreover, the fact that Kucera discloses the R_2 group as a $\text{C}_6\text{-C}_{18}$ alkyl group would not motivate one of ordinary skill in the art to include a $\text{C}_1\text{-C}_5$ alkyl group as recited by the instant claims.

Accordingly, Kucera does not render the claimed invention obvious. Therefore, Applicants respectfully request that the rejection of claims 1-8 and 39 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

V. The Double Patenting Rejections

Claims 1-8 and 39 are rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1-4 of U.S. Patent No. 5,962,437, claims 12, 17, 18, and 19 of U.S. Patent No. 7,026,469, and claims 1-11 and 14-18 of U.S. Patent No. 7,141,557. The Examiner alleges that although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed subject matters overlap the scope.

While Applicants do not necessarily agree with this ground for rejection, in order to expedite the prosecution of this application to allowance, a Terminal Disclaimer is being filed herewith relative to U.S. Patent Numbers 5,962,437; 7,026,469; and 7,141,557. However, this Terminal Disclaimer is being submitted with the understanding that the filing of this Terminal Disclaimer is not intended to be, and does not constitute, an admission that an obviousness-type double patenting rejection would be proper between the claims of this reference and the presently claimed invention. (*See* MPEP 804.02 II).


VI. Conclusions

It is respectfully submitted that the rejections to the claims have been overcome. Should the Examiner disagree, Applicants respectfully request a telephonic or in-person interview with the undersigned attorney to discuss any remaining issues and to expedite the eventual allowance of the claims.

Except for issues payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-0310.

Dated: **October 27, 2008**
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Respectfully submitted,
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